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EXAMINER	
LUM, LEON YUN BON	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 03/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/031,988	NADAOKA ET AL.	
	Examiner	Art Unit	
	Leon Y. Lum	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *25 January 2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed 17 December 2003 is acknowledged and has been entered.

Priority

2. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Japan on 26 May, 2000. It is noted, however, that applicant has not filed a certified copy of the 2000-157049 application as required by 35 U.S.C. 119(b).

Information Disclosure Statement

3. The information disclosure statement filed 06 May 2002 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because documents 9-178748 and 9-506434 do not have English translations. The documents have been placed in the application file, but the information referred to therein has not been considered as to the merits. With respect to the 10-274624, 10-274653, and 8-285849 documents, only the abstracts have been considered since English translations have not been provided for the rest of the documents. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement,

including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

Claim Objections

4. Claims 6, 21, and 25 are objected to because of the following informalities: There is no period at the end of the claims. Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. In claim 1, lines 4-5, the phrase "the development of the inspection target solution" is vague and indefinite. The specification does not define the term "inspection target solution" and it is unclear as to how the solution is developed. On page 1 of the specification, the 3rd paragraph states that "an inspection target solution is applied" on an "immuno-chromatographic sensor", which indicates that the solution is added to the sensor. However, the specification does not provide a definition on how the inspection

target solution is developed and it is unclear how the term "development" limits the inspection target solution.

8. In claim 1, lines 10-12, and in claim 2, lines 7-9, the phrase "a space forming part which forms a cavity part that is a space into which the inspection target solution flows, between the development layer and the space forming part" is vague and confusing. Since the initial part of the phrase claims that the space forming part forms a cavity part in which the solution flows therein, it would imply that the solution flows ***within*** the space forming part since the cavity part is formed by the space forming part. However, the later part of the phrase claims that the inspection target solution flows ***between*** the development layer and the space forming part, which contradicts the previous claim of the cavity part being within the space forming part. What is exactly being claimed?

9. In claims 4 and 23, line 2, the phrase "defines the amount" is vague and indefinite. The specification does not define the phrase and it is not clear what the phrase means. How does the phrase relate to the "amount of the flowing-in" (line 2)?

10. In claims 4-5, 10, 17, 23-24, 29, and 36, line 2, the term "flowing-in" is vague and indefinite. The specification does not define the term and it is unclear as to what the term means. How does the term limit the "inspection target solution" (line 2)?

11. In claims 5 and 24, lines 2-3, the phrase "enough to develop in the development layer" is vague and confusing. It is unclear how the phrase limits the "cavity part" (line 2). It also seems as if certain terms or phrases are absent that would render the phrase less confusing with the rest of the claim.

12. In claims 9 and 28, line 2, the term "(microliter)" is vague and indefinite. It is unclear how the term limits the instant claim. Is the term a part of the "volume" (line 2)?

13. In claims 15 and 34, the phrase "the bottom surface of the specimen holding part is as high as or higher than that of the cavity part is vague and indefinite. It is not clear from the specification what the bottom surface of the specimen holding part is and in what reference to the cavity part the phrase "as high or higher than that of the cavity part" applies. In the specification, page 29, 5th paragraph, pages 31-32, and Figures 6a-b indicate that the specimen holding part 17a is on base material 17. Which is the bottom surface of the specimen holding part? Is it on the dotted square, as shown in Figure 6a or on a different side of base material 17? In addition, cavity part 1 is shown to be adjacent and ***above*** specimen holding part 17a. Since the cavity part is above the specimen holding part, how can a surface of the specimen holding part be higher than that of the cavity part? Applicant is invited to clarify the claim and render it less indefinite and confusing.

14. In claims 19 and 38, the phrase "and they are entirely in a dry state" is vague and indefinite. The specification does not define the phrase and it is unclear what the phrase refers to. Does the term "they" refer to the "whole reagents" (line 2), the "reagent" (line 2) and "marker reagent" (lines 2-3), or to another embodiment?

15. Claims 1-2 recite the limitation "the inspection target solution" in line 2 of claim 1 and lines 2-3 of claim 2. There is insufficient antecedent basis for this limitation in the claim.

16. Claims 4-5, 17, 23-24, and 36 recite the limitation "the flowing-in" in line 2. There is insufficient antecedent basis for this limitation in the claim.

17. Claims 14-15 and 33-34 recite the limitation "the specimen holding part" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

18. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

19. Claims 1-2 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Burd et al (US 5,939,331).

In the instant claims, Burd et al reference teaches a device (i.e. biosensor) with a test strip 13 (i.e. development layer) that contains a label zone 26 (i.e. marker reagent holding part) and a capture zone 29 (i.e. reagent immobilization part), wherein the capture zone 29 contains at least one capture reagent capable of interaction with the label after sample fluid moves from sample zone 23 through label zone 26 to capture zone 29 (i.e. marker reagent can be eluted by the development of the inspection target solution). See column 8, line 2 to column 10, line 14; and Figures 1-2. In addition, Burd et al reference teaches a top cover 17 (i.e. space forming part) with sample introduction aperture 35 (i.e. cavity part) that allows for the introduction of the sample into the sample zone 23 (i.e. a space into which the inspection target solution flows, between the development layer and the space forming part), wherein the label zone 26 is above and slightly overlapping the sample zone 23 (i.e. marker reagent holding part in the cavity part). See column 9, lines 33-43 and column 10, lines 4-7; and Figures 1-2.

With respect to claim 2, since the introduction aperture 35 (i.e. cavity part) is placed directly over the sample zone 23, and the label zone 26 (i.e. marker reagent holding part) overlaps the sample zone 23, as stated above, the label zone 26 is also therefore under the introduction aperture 35, and reads on the limitation of "marker reagent holding part in the cavity part" (lines 10-12).

With regards to claims 3-5, 10, 22-24, and 29, Burd et al reference teaches that the sample introduction aperture 35 (i.e. cavity part) allows for the introduction of the

sample into the sample zone 23, wherein the sample then flows through label zone 26 and into capture zone 29 (i.e. defines the amount of the flowing-in of the inspection target solution by the volume of the cavity part; has a volume for the flowing-in of the inspection target solution enough to develop in the development layer), as stated above. See column 9, lines 33-43 and column 10, lines 4-7; and Figures 1-2. Since the fluid does not stay in the introduction aperture 35, the aperture does not permanently contain the fluid (i.e. the cavity part temporarily holds the inspection target solution; means for checking on flowing-in of the inspection target solution).

With regards to claims 11 and 30, Burd et al reference teaches that the top cover 17 (i.e. space forming part) includes an indicator aperture 37 that is on top of window 15 wherein the binding of label can be observed through a thin, clear or translucent material (i.e. partially light permeable). See column 9, lines 33-36 and Figure 1.

With regards to claims 12 and 31, Burd et al reference teaches that the sample zone 23 contains reagent capable of binding and retaining red blood cells while allowing RBC-free fluid to flow into the remainder of the device (i.e. a separation part). See column 9, lines 57-62.

With regards to claims 13, 15, 32, and 34, Burd et al reference teaches sample zone 23 (i.e. a specimen holding part) below introduction aperture 35 (i.e. cavity part), as stated above. See column 9, lines 57-58 and Figure 1. Since claims 15 and 34 are vague and indefinite as described in the rejection based on 35 USC 112, second paragraph above, the claims are interpreted as claiming a part of the specimen holding part that is as high or higher than the cavity part. Since introduction aperture 35 (i.e.

cavity part) is empty space in embodiment 17, which is placed on top of embodiment 13 that contains sample zone 23 (i.e. specimen holding part), the top surface of the sample zone would be at least on the same level as a part of the introduction aperture.

With regards to claims 17 and 36, Burd et al reference teaches a series of slits 39 in the top cover 17 for the evaporation of fluid from the absorbent zone (i.e. an air vent). See column 9, lines 46-47 and Figure 1. With regards to the phrase "for assisting the flowing-in of the inspection target solution in the cavity part" in the instant claims, the phrase is an intended use of the limitation "air vent" and is therefore not given patentable weight.

With regards to claims 18 and 37, Burd et al reference teaches that the membranes employed may allow for either bibulous or non-bibulous flow, wherein non-bibulous membranes will have a pore size of about 1-00 μm (i.e. a porous material which can be permeated by permeation of the inspection target solution in the cavity part). See column 2, line 67 to column 3, line 48.

With regards to claims 20-21 and 39-40, Burd et al reference teaches the flow of sample fluid through label and capture zones on nitrocellulose with reagent antibodies and label that bind and indicate the presence of analyte (i.e. employed for a one-step immuno-chromatography). See column 9, line 33 to column 10, line 14.

Claim Rejections - 35 USC § 103

20. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

21. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

22. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

23. Claims 6 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burd et al (US 5,939,331) in view of Bernstein et al (US 5,824,268).

Burd et al reference has been disclosed above, and teaches that sample zone 23 contains reagents that retain red blood cells (i.e. part in the cavity), as stated above, but fails to teach that sample zone 23 contains a cell component destruction reagent.

Bernstein et al reference teaches a membrane treated with a buffer containing 0.1 M ammonium chloride to lyse red blood cells, in order to deliver sample to the test strip that is essentially plasma with little contamination from whole red blood cells. See column 10, lines 49-54.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Burd et al with a membrane treated with a buffer containing 0.1 M ammonium chloride to lyse red blood cells, as taught by Bernstein et al, in order to deliver sample to the test strip that is essentially plasma with little contamination from whole red blood cells. One of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in including a membrane containing ammonium chloride to lyse red blood cells, as taught by Bernstein et al, in the device of Burd et al, since Burd et al teach the prevention of red blood cells from flowing past the sample zone 23 (i.e. part in the cavity), and a membrane that lyses red blood cells is one type of device to prevent passage of red blood cells.

24. Claims 7 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burd et al (US 5,939,331) in view of Killeen et al (US 5,166,051).

Burd et al reference has been disclosed above, and teaches that sample zone 23 contains reagents that retain red blood cells (i.e. part in the cavity), as stated above, but fails to teach that sample zone 23 contains a cell component shrinkage reagent.

Killeen et al reference teaches a crenating agent in a membrane that functions to shrink RBC, in order to rigidify cells to make them less flexible so that they become trapped at the surface of a detection membrane and allow only the liquid analyte composition to flow through the membrane and penetrate the detection zone to provide to a viable signal. See column 5, lines 36-47.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Burd et al with a crenating agent in a membrane that functions to shrink RBC, as taught by Killeen et al, in order to rigidify cells to make them less flexible so that they become trapped at the surface of a detection membrane and allow only the liquid analyte composition to flow through the membrane and penetrate the detection zone to provide to a viable signal. One of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in including a membrane containing a crenating agent to shrink cells, as taught by Killeen et al, in the device of Burd et al, since Burd et al teach the prevention of red blood cells from flowing past the sample zone 23 (i.e. part in the cavity), and a membrane that crenates cells is one type of device to prevent passage of cells.

25. Claims 8 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burd et al (US 5,939,331) in view of Barr (US 4,252,538).

Burd et al reference has been disclosed above, and teaches that sample zone 23 contains reagents that retain red blood cells (i.e. part in the cavity), as stated above, but fails to teach that sample zone 23 contains a bleaching reagent.

Barr reference teaches distilled water that bleaches red blood cells, in order to cause rupture of the membrane and produce transparent red blood cells. See column 10, lines 14-35.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Burd et al with distilled water that bleaches red blood cells, as taught by Barr, in order to cause rupture of the membrane and produce transparent red blood cells. One of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in including in the device of Burd et al, since Burd et al teach an immunochromatographic assay with the prevention of whole red blood cells from flowing past the sample zone 23 (i.e. part in the cavity), and the distilled water of Barr causes the lysis of red blood cells, and is one means of preventing whole red blood cells from flowing past the sample zone 23 such that the transparent red blood cells would not affect detection of coloration in the immunochromatographic assay.

26. Claims 9, 28, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burd et al (US 5,939,331) in view of Allen et al (US 5,416,000).

Burd et al reference has been disclosed above, but fails to teach that the cavity part has a volume of 20 μl or less.

Allen et al reference teaches a sample receiving element that receives about 10 μl volume of blood, in order to receive one or a series of small drops of blood. See column 5, lines 19-33.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify he apparatus of Burd et al with a sample receiving element that receives about 10 μl volume of blood, as taught by Allen et al, in order to receive one or a series of small drops of blood. One of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in including a sample receiving element that receives about 10 μl volume of blood, as taught by Allen et al, in the device of Burd et al, since both Burd et al and Allen et al disclose blood as sample fluid, and the sample receiving element of Allen et al is in an immunochromatographic test strip. See column 7, line 41.

27. Claims 14 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burd et al (US 5,939,331) in view of Woudenberg et al (US 6,124,138).

Burd et al reference has been disclosed above, but fails to teach that the specimen holding part holds a larger amount of inspection target solution than the volume of the cavity part.

Woudenberg et al reference teaches a dead-end fluid connection 86 (i.e. cavity part) dimensioned to define a volume that is substantially less than the volume of the

associated detection chamber 84 (i.e. specimen holding part), in order to ensure that the detection chamber is sufficiently filled with sample. See column 9, lines 3-14 and Figure 5.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Burd et al with a dead-end fluid connection 86 (i.e. cavity part) dimensioned to define a volume that is substantially less than the volume of the associated detection chamber 84 (i.e. specimen holding part), as taught by Woudenberg et al, in order to ensure that the detection chamber is sufficiently filled with sample. One of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in including a fluid connection with less volume than a detection chamber, as taught by Woudenberg et al, in the method of Burd et al, since Burd et al teach the transfer of fluid from the introduction aperture (i.e. cavity part) to the sample zone (i.e. specimen holding part) is from an opening to an interior chamber, and the fluid connection and detection chamber of Woudenberg are, respectively, an opening and interior chamber.

28. Claims 19 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burd et al (US 5,939,331) in view of Kloepfer (US 4,883,764).

Burd et al reference has been disclosed above, but fails to teach that whole reagents including the reagent in the reagent immobilization part and the marker reagent are in a dry state and they are entirely in a dry state.

Kloepfer reference teaches reagents in dry form on the test strip, in order to improve the chemical stability of the reagents. See column 6, lines 26-32.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Burd et al with reagents in dry form on the test strip, as taught by Kloepfer, in order to improve the chemical stability of the reagents. One of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in including dry reagents, as taught by Kloepfer, in the apparatus of Burd et al, since both Burd et al and Klopefer teach test strips.

Double Patenting

29. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

30. Claims 1-40 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of copending Application No. 10/069,845 in view of Burd et al (US 5,939,331).

Claims 1-40 of the instant application recite a biosensor which includes, in parts of a development layer for developing the inspection target solution, a reagent immobilization part immobilized therein and a marker reagent holding part where a marker reagent which can be eluted by the development of the inspection target solution is held in the cavity part, and measures a bonding amount of the marker reagent in the reagent immobilization part, thereby qualitatively or quantitatively measuring components to be measured in the inspection target solution, further including a space forming part which forms a cavity part that is a space into which the inspection target solution flows, between the development layer and the space forming part.

Claims 1-25 of the copending application discloses a biosensor comprising a development layer wherein an inspection target solution is developed, and further comprising at least a marker reagent part where a marker reagent is held so as to be dissolved by the development of the inspection target solution in a part of the development layer, as well as a reagent immobilization part where a reagent which specifically reacts to an analysis target in the inspection target solution is immobilized in a part of the development layer. Claims 1-25 of the copending application also disclose directional permeation of the inspection target solution. With regards to the limitation "measures a bonding amount of the marker reagent in the reagent immobilization part, thereby qualitatively or quantitatively measuring components to be measured in the inspection target solution" in the instant application, since the copending application is a biosensor that develops an inspection target solution and

also comprises a marker reagent part and reagent immobilization part, the device of the copending application would necessarily have the capability of measuring "a bonding amount" between the marker reagent and the reagent immobilization part, which would inherently include either "qualitatively or quantitatively" measuring components in the inspection target solution.

However, claims 1-25 of the copending application fails to teach a space forming part which forms a cavity part that is a space into which the inspection target solution flows, between the development layer and the space forming part, and also fails to teach that the marker reagent is held in the cavity part.

Burd et al reference teaches a top cover 17 (i.e. space forming part) with sample introduction aperture 35 (i.e. cavity part) to allow for the introduction of the sample into a sample zone 23 (i.e. between the development layer and the space forming part), in order for sample to interact with the sample zone prior to a label zone and other parts of the biosensor. In addition, Burd et al reference teaches that the label zone 26 is above and slightly overlapping the sample zone 23 (i.e. marker reagent holding part in the cavity part). See column 9, lines 33-43 and column 9, line 57 to column 10, line 14; and Figures 1-2. Since the introduction aperture 35 (i.e. cavity part) is placed directly over the sample zone 23, and the label zone 26 (i.e. marker reagent holding part) overlaps the sample zone 23, as stated above, the label zone 26 is also therefore under the introduction aperture 35, and reads on the limitation of "marker reagent holding part in the cavity part".

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus in claims 1-25 of the copending application with a top cover 17 (i.e. space forming part) with sample introduction aperture 35 (i.e. cavity part) to allow for the introduction of the sample into a sample zone 23 (i.e. between the development layer and the space forming part), as taught by Burd et al, in order for sample to interact with the sample zone prior to a label zone and other parts of the biosensor. One of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in including a top cover with sample introduction aperture over a sample zone, as taught by Burd et al, with claims 1-25 of the copending application since claims 1-25 of the copending application teach a biosensor with parts that interact with an inspection target solution in series, and the introduction of sample through a sample introduction aperture in a top cover, as taught by Burd et al, is one type of method to introduce a target solution into a biosensor at one location for interaction with different biosensor parts in series.

This is a provisional obviousness-type double patenting rejection.

31. The above provisional obviousness-type double patenting rejection is representative of double patenting rejections that are necessary between the instant application and a number of copending applications. The following list discloses the serial numbers of the other copending applications which would require similar provisional obviousness-type double patenting rejections as applied supra: 10,133,698

(claims 1 and 3-17); 10,398,711 (claims 1-19); 10,048,727 (claims 1-11); 10,116,407 (claims 1-5); 10,242,672 (claims 14-17).

Conclusion

32. No claims are allowed.

33. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure:

McGeehan et al (US 5,234,813) teach an absorbent dipstick with a sample well and immunochromatographic detection means.

Good et al (US 6,194,224 B1) teach a diagnostic test strip with a sample receiving zone, a reagent zone, and a test zone.

34. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon Y. Lum whose telephone number is (571) 272-2878. The examiner can normally be reached on 8:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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